

DEPARTMENT OF HEALTH & HUMAN SERVICES
PURGED BAK

Public Health Service

MD94Bn

September 8, 1999

WARNING LETTER

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99-47

Patrick L. Soderlund
President
St. Mary's Chemical
201 South 3rd Street
St. Peter, MN 56082

Dear Mr. Soderlund:

An inspection of your bulk drug repackaging facility located in St. Peter, Minnesota on May 17, 18, 20 & 25, 1999 by our investigator found that you are repacking and distributing active pharmaceutical ingredients which are in violation of Section 501(a)(2)(B) and 502(f)(1) of the Federal Food, Drug and Cosmetic Act (the Act).

Section 501(a)(2)(B) of the Act requires that drugs, including active pharmaceutical ingredients, be processed in such a manner to assure that they are not adulterated and that such drugs meet the quality and purity characteristics, which they purport or are represented to possess.

Our investigator identified the following problems with your repackaging operation:

1. No identification tests are performed on each new lot of raw material.
2. The reliability of the suppliers certificates of analysis have never been verified.
3. Packaging operations do not preclude the contamination of all drug products repacked at your firm with ampicillin or amoxicillin.
4. No data exists to support expiration dates on some of your labels.
5. Scales used to repackage active pharmaceutical ingredients have not been calibrated.

Patrick L. Soderlund
September 8, 1999

Section 502(f)(1) requires that drugs bear adequate directions for use. The active pharmaceutical ingredients (bulk drugs) sold by you do not bear "adequate directions for use". Bulk drugs – for which directions for use may be impractical or unnecessary, because they will undergo further processing prior to use – may be exempted from the "adequate directions for use" requirement if they meet the conditions established in Title 21, Code of Federal Regulations, Section 201.122 (21 CFR 201.122), "Drugs for Processing, Repacking or Manufacturing." Bulk drugs sold by you are not entitled to this exemption because the "exemption does not apply to a substance intended for use in manufacture, processing or repacking which causes the finished article to be a new animal drug unless a new animal drug application covers the production and delivery of the drug substance to the application holder." Several of the bulk drugs distributed to Vet Rx were used to make unapproved new animal drugs for food animals. You are responsible for selling misbranded drugs to them. It is your responsibility as a distributor of bulk animal drugs, which do not bear adequate directions for use, to assure they are covered by an exemption before they are shipped.

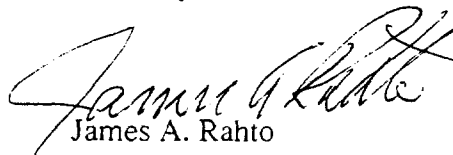
The above is not intended to be an all-inclusive list of violations. As a repacker of active pharmaceutical ingredients you are responsible for assuring that your overall operation and the products you repackage and distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, or the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Compliance Officer Robert P. Senll at the address indicated on the letterhead.

Sincerely,


James A. Rahto
District Director
Minneapolis District

RPS/rfk